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EXAMINER

KIM, YOUNG J

ART UNIT PAPER NUMBER

1637

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/627,780

Applicant(s)

FAN, KEJUN

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/5/03</u> . | 6) <input type="checkbox"/> Other: ____.  |

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## DETAILED ACTION

### *Preliminary Remark*

While there are no rules governing whether a number or an alphabet should be used when enumerating steps of a method, it is advisable that alphabet be used for enumerating such steps so as to avoid their confusion with claim numbers.

### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

### *Information Disclosure Statement*

The IDS received on December 5, 2003 is acknowledged.

A signed copy of the PTO-1449 is enclosed here with.

### *Drawings*

No drawing(s) is/are filed for the application.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for reciting the phrase, “a step of binging the sample...with,” because it is unclear how a sample is “binged” with something. When read in light of the specification, this phrase appears to contain a typographical error and that the word, “binging” is meant to recite the word, “bringing.” This interpretation is assumed for the purpose of prosecution.

Claim 1 is indefinite because it is unclear whether the phrase, “separating the solid-phase carrier from the sample,” (appearing in step (3)), intends to mean that the solid-phase carrier to which the nucleic acids are bound (as recited in step (2)), or that the solid-phase carrier unbound to nucleic acids are separated. For the purpose of prosecution, the former interpretation is assumed.

Claims 2-5 are indefinite by way of their dependency on claim 1.

Claim 6 is indefinite because the claim recites a further step (5), which elutes the nucleic acids adsorbed onto the solid-phase carrier, when the parent claim 1 only contains three steps, rendering the claim indefinite in its metes and bounds as to what step is conducted therebetween. For the purpose of compact prosecution, claim 6 is assumed to be dependent on claim 5<sup>1</sup>.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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<sup>1</sup> This interpretation appears to be the most reasonable as the water-insoluble solid-phase carrier-nucleic acid complex must first be washed prior to eluting the nucleic acid therefrom.

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Dzieglewska et al.

(WO 96/18731, published June 20, 1996; IDS ref # AS).

Dzieglewska et al. disclose a method of isolating a nucleic acid from a sample comprising nucleated cells (eukaryotic cells, *see* page 6, lines 3-17), wherein said method comprises the steps:

a) bringing the sample with a lysis solution (page 6, bottom paragraph), wherein said lysis solution comprises a detergent (or a surfactant) as well as enzymes which breakdown cellular wall, such as proteinase K (*see* page 7, lines 2-5), so as to release the nucleic acid from the cells (*see* page 7, where artisans explicitly state that “if other agents such as enzymes eg. proteinase K are being used, they may be included in with the detergent”);

b) the sample is contacted with a water-insoluble solid-phase carrier (or a solid phase; *see* page 6, bottom paragraph), wherein said solid phase is explicitly disclosed as being polymeric beads (page 9, 3<sup>rd</sup> and 4<sup>th</sup> paragraph), wherein said beads are spherical and having a diameter of about 10  $\mu\text{m}$  (page 9, 4<sup>th</sup> paragraph), particularly Dynabeads® (page 11, lines 1-2), further wherein the nucleic acids of the sample are adsorbed onto the beads (*see* page 34, line 8 which evidences that the binding is via adsorbing); and

c) separating the solid-phase carrier from the sample (page 34, lines 13-15; page 12, lines 1-2), thereby clearly anticipating instant claim 1.

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With regard to claim 2, the artisans explicitly state that proteinase K is employed (page 7, lines 2-5).

With regard to claim 3, the detergent is disclosed as being “ionic, including anionic and cationic, non-ionic or zwitterionic,” wherein artisans explicitly state that “[a]nionic detergents have been shown to work particularly well...” (page 7, bottom paragraph).

With regard to claim 4, Dynabeads®, employed by the artisans (page 11, lines 1-2), as discussed below, is made of polystyrene.

With regard to claim 5, after the separation of the solid-phase carrier from the sample, the solid-phase carrier is washed (page 11, bottom paragraph to page 12, line 4).

With regard to claim 6, the artisans state that the nucleic acids bound to the solid-phase carrier are eluted (page 12, 4<sup>th</sup> paragraph).

With regard to claim 7, the artisans state that the reactants and components required to perform the method of their invention is provided in a kit form (page 14, lines 4<sup>th</sup> paragraph).

Therefore, the invention as claimed is clearly anticipated by Dzieglewska et al.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 7 is rejected under 35 U.S.C. 102(a) and (e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Belley et al. (U.S. Patent No. 6,469,159 B1, issued October 22, 2002, filed April 26, 1999).

Claim 7 is rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Claim 7 is drawn to a kit. A kit is defined by its elements, as the intended use for the kit is not given patentable weight. So long as a reference teaches all elements of the kit recited in the claim, said reference would be prior art.

Belley et al. disclose a combination of reagents, said combination comprising:

- a) a cellular component-degrading enzyme (*i.e.*, protease, *see* claim 1; column 3, line 52; and claim 6);
- b) a water-insoluble solid-phase carrier (or polystyrene beads; *see* column 7, lines 22-23);
- c) a nonionic surfactant (column 3, line 52); and
- d) water-soluble organic solvent (column 3, lines 54-61).

As the combination are employed together in a single method, such combination would anticipate a kit comprising the same elements.

In the alternative, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to package the compositions of Belley et al. into a kit in view of the conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, matched and/or preweighed components, etc.

Therefore, the invention as claimed is anticipated, or in the alternative, obvious over the cited reference.

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Claims 1, 2, and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belley et al. (U.S. Patent No. 6,469,159, issued October 22, 2002, filed April 26, 1999) in view of Caldarelli-Stefano et al. (Journal of Clinical Pathology, 1999, vol. 52, pages 158-160) as evidenced by Warburton et al. (Laboratory Procedures MFLP-90, April 1997, pages 1-2; Google® [online]. Retrieved on December 19, 2005 from Google®).

Belley et al. disclose a method of separating nucleic acid from paraffin embedded tissues (thus nucleated cells; *see* column 7, lines 45-46), wherein said method involves the steps: a) contacting the paraffin sample containing the nucleated cells with a lysis solution containing a protease (column 7, line 50; thus “a cellular component-degrading enzyme) and a surfactant (Tween20®; *see* column 7, line 49; column 4, lines 44-46; and claim 5).

With regard to instant claim 2, the cellular component-degrading enzyme employed by Belley et al. is disclosed as being a protease (column 7, line 50).

Belley et al., upon lysis of the cell, isolates the nucleic acids released from said cell via centrifugation (*see* claim 1 on column 12, lines 59-60) and hence, **do not** teach a step of binding the sample with a water-insoluble solid-phase carrier that adsorb and bind nucleic acids thereon and isolation of the nucleic acids via separating the solid-phase carrier from the sample (limitation of instant claim 1, steps (2) and (3)).

Belley et al. **do not** teach that the water-insoluble carrier comprises at least one compound selected from the group recited in instant claim 4.

Belley et al. **do not** teach that after the separation (or isolation) of nucleic acids (attached to the water-insoluble solid-phase carrier) from the sample, the separated water-insoluble solid-phase carrier is washed.



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Caldarelli-Stefano et al. teach a method of isolating nucleic acid from a paraffin embedded tissue, wherein said method employs Dynabeads (from Dynal®) for adsorbing DNA thereto (page 159, 1<sup>st</sup> column, 1<sup>st</sup> paragraph). In that method, the paraffin comprising the embedded tissue is dissolved and the cells are lysed (page 159, 1<sup>st</sup> column, 1<sup>st</sup> paragraph, 5<sup>th</sup> line).

With regard to claim 5, Caldarelli-Stefano et al. washes the DNA-Dynabead complex with 200 µl of washing buffer (page 159, 1<sup>st</sup> column, 1<sup>st</sup> paragraph, lines 12-13).

With regard to claim 6, Caldarelli-Stefano et al. elutes the DNA from the DNA-Dynabead complex (page 159, 1<sup>st</sup> column, 1<sup>st</sup> paragraph, bottom through page 159, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph).

With regard to claim 4, as evidenced by Warburton et al., Dynabeads® from Dynal® is disclosed as being made of polystyrene (*see* 1<sup>st</sup> page of the print out).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Belley et al. with the teachings of Caldarelli-Stefano et al., thereby arriving at the claimed invention for the following reasons.

While Belley et al. disclose a method of extracting nucleic acid from paraffin embedded tissues via use of a combination of surfactant and lysis reagent, involved in a cumbersome method employing toxic reagents, such as phenol/chloroform extraction (*see* page 158, 1<sup>st</sup> column, bottom paragraph of Caldarelli-Stefano et al.), the artisans employ a traditional means of isolating the nucleic acid from the sample/buffer mixture, which involves centrifugation (see claim 1 of Belley et al.).

Caldarelli-Stefano et al. are explicit in stating the advantages associated with employing bead assisted nucleic acid isolation:

“Our data support the use of a magnetic bead based procedure as a rapid method of extracting DNA from formalin fixed, paraffin embedded archival tissues suitable for PCR amplification...” (page 159, 2<sup>nd</sup> column, bottom paragraph), wherein “[e]xtraction using magnetic

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beads is easy and time saving, and does not require potentially dangerous procedures or specialized laboratory equipment..." (page 160, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph).

Hence, one of ordinary skill in the art would have been clearly motivated to combine the teachings of Belley et al. with the teachings of Caldarelli-Stefano et al. so as to arrive at a method involving magnetic bead assisted DNA isolation, thereby avoiding time consumption involved in the step of centrifugation and the cost of purchasing a centrifugation machine.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

### ***Conclusion***

No claims are allowed.

### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED,

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so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim  
Patent Examiner  
Art Unit 1637  
12/30/2005

**YOUNG J. KIM**  
**PATENT EXAMINER**

yjk